EXHIBIT 1
TO
VEN-A-CARE'S UNOPPOSED MOTION FOR LEAVE TO FILE SUR-REPLY IN RESPONSE TO SUN HAMILTON REPLY TO RESPONSE TO THEIR MOTION TO REOPEN THE JUDGMENT AND FOR A HEARING

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Master Docket 01-cv-12257-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc. v. Baxter Healthcare Corporation and Baxter International, Inc.*	)	Subcategory 06-11337
	)	Case No: 10-cv-11186-PBS
	)	Judge Patti B. Saris

Sur-Reply of Ven-A-Care of the Florida Keys, Inc.

Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") files the following sur-reply to the Reply of Rule 60 (b) (6) Non-Party Movants Sun and Hamilton.

1. Sun and Hamilton paint the Ven-A-Care Baxter Settlement in a false light.

Sun and Hamilton have sought from the beginning of this controversy to cast Ven-A-Care's settlement with Baxter in the false light of stealth and underhandedness. In their most recent filing they decry the settling parties' "secretive inclusion of Advate" and "settlement sleight-of-hand," and once again depict themselves as having been blindsided by the possibility that their Advate claim could be affected by the resolution of this action. Like the previous

discredited assertions that Sun and Hamilton were deprived of timely notice of the terms of Ven-A-Care's settlement, it is a false premise unsupported by fact.

As Ven-A-Care has pointed out before, Ven-A- Care, Baxter, the Department of Justice, *and Sun/Hamilton* were specifically aware, well before settlement negotiations concluded, that Ven-A-Care wished to settle its entire action against Baxter; that it was legally debatable whether Ven-A-Care or Sun/Hamilton were "first to file" as to Advate; and that it was thus uncertain whether the Sun/Hamilton qui tam claims were even jurisdictionally viable. Moreover, all concerned were well aware that a Ven-A-Care settlement of its entire action against Baxter would resolve Baxter's liability for all drugs and biological products encompassed by that action. All concerned were also aware that Ven-A-Care could not resolve Sun and Hamilton's first-to-file problems through its settlement because no party has the power to invest the Court with subject matter jurisdiction. Sun and Hamilton were thus presented with a choice: attempt to reach a settlement with Baxter or accept the risk of a judicial determination of their first-to-file status. Sun and Hamilton chose the latter course.

Ven-A-Care's position has been consistent, transparent and candidly communicated to all concerned: a.) It sought to settle its entire FCA qui tam action against Baxter, which would have included Advate if it was encompassed by Ven-A-Care's earlier filed case. b.) If Sun or Hamilton was first-to-file FCA qui tam claims as to Advate, then Advate FCA qui tam claims were not encompassed by Ven-A-Care's action and hence were not encompassed by its Settlement. c.) If the Court disagrees with Ven-A-Care's construction and determines that the Settlement may be invalid because it settled FCA qui tam claims another relator was first to file, then the Severability Clause at Paragraph 20 requires that the offending subject matter simply be

deemed excluded from the Settlement. d.) 31 U.S.C. 3730 (b) (5) precludes Sun and Hamilton from seeking relief in Ven-A-Care's FCA qui tam action and such intercession is unnecessary because Ven-A-Care did nothing to prejudice their rights for the reasons stated above. e.) Because Ven-A-Care has been forced into an adversarial proceeding with Sun and Hamilton, it must make the additional arguments it believes to be most accurate and appropriate given the facts and the current state of the law. Those additional arguments are that Advate is encompassed by Ven-A-Care's earlier filed FCA qui tam action for purposes of the 31 U.S.C. § 3730 (b) (5) first-to-file bar in light of the First Circuit's 2009 decision in *Duxbury* and Sun and Hamilton otherwise lack standing to contest Ven-A-Care's Settlement. Even if Sun and Hamilton had standing to force the reopening of Ven-A-Care's closed case, given the facts, law and litigation risks applicable to the post-2002 Advate claims, the Settlement is still fair, adequate and reasonable.

2. Ven-A-Care exposed the specifics of Baxter's recombinant, blood factor VIII, fraud several years before Sun and Hamilton did.

The decisions of this Court in *U.S. ex rel Ven-A-Care v. Abbott Laboratories* and the First Circuit in *Duxbury* require a comparison of Ven-A-Care's earlier allegations with those in the later Sun/Hamilton Complaint to determine if Sun and Hamilton alerted the government to a new "fraudulent scheme." The chart attached hereto as Exhibit A contains excerpts from the pertinent pricing fraud allegations in (a) Ven-A-Care's 2002 complaint and (b) Sun/Hamilton's 2005 complaint. Recombinate was named specifically by Ven-A-Care in all of its sealed complaints, commencing in 1997, as one of the drugs with which Baxter practiced its pricing

fraud on government health care programs, and Recombinate was also specifically identified by Ven-A-Care as having a 41% spread. See Exhibit 2 of the Ven-A-Care Fourth Amended Complaint filed December 11, 2002, Docket Entry 8205-3. Sun and Hamilton erroneously state that Ven-A-Care merely alleged the name "Recombinate," ignore Ven-A-Care's specific allegations about the inflated spread on Recombinate, and fail to acknowledge that their later allegation of a Recombinate spread is remarkably similar to that previously alleged by Ven-A-Care. Additionally, Ven-A-Care's 1997 Second Amended Complaint included a specific example of Baxter's false Recombinate price reporting as an illustration of the fraud scheme. (See, Notice Of Filing Pleading From Transferor Court's File; Case 1:10-cv-21745-ASG Document 5 Entered on FLSD Docket 06/04/2010.)

Ven-A-Care's years-earlier allegations informed the government of Baxter's widespread false drug and biological product pricing scheme and specified that Recombinate was one of the exploited biological products. Sun/Hamilton's later action, by including more recently FDA-approved and closely related Advate, added a detail – not a new or different scheme or different essential elements of fraud – and the absence of Advate from Ven-A-Care's pleadings is of no significance. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc., 149 F.3d 227 (3d Cir. 1998). The first-to-file rule is "exception-free," Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13, 33-34 (1st Cir. 2009) (citing U.S. *ex rel.* Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1188 (9th Cir. 2001)), and Ven-A-Care's pleadings and its statutory disclosures of evidence to the Department of Justice had long since put the government on the trail of Baxter's fraud. "[O]nce the government knows the essential facts of a fraudulent scheme, it has enough information to

discover related frauds." LaCorte v. SmithKline Beecham Clinical Laboratories, Inc., 149 F.3d 227, 234 (3d Cir. 1998).

3. This Court's 2008 order on the Abbott Laboratories first-to-file motion does not support Sun/Hamilton.

Sun/Hamilton's proposed application of this Court's July 15, 2008 Memorandum and Order denying Abbott's motion for certification of an immediate appeal ignores the essential facts and is contrary to the First Circuit's decision in *Duxbury*. The Abbott case involved the uncommon circumstance of a defendant invoking a relator's own, earlier-filed action as a first-to-file bar against the same relator's subsequent action. As this Court noted in finding that Ven-A-Care's earlier-filed (Florida) action did not bar its later action including Erythromycin, "The complaint in the Florida Case involved different drugs marketed by a different division of Abbott. Significantly, Erythromycin is primarily a self-administered drug and the other drugs are generally administered by physicians." U.S. *ex rel.* Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., C.A. No. 07-11618-PBS, Memorandum and Order at 7 (D. Mass. 2008).

Sun and Hamilton point to the next lines in this Court's *Abbott* decision in support of the contention that a drug must be alleged by name to be encompassed for first to file purposes. ("Notice of fraud in one drug's pricing is not notice of fraud in another drug's pricing, as Abbott well knows. This is because drugs are often marketed, reimbursed, sold, and priced in different ways."). However, the First Circuit's 2009 *Duxbury* decision makes it clear that a drug not specifically named in the first relator's complaint (like the unnamed lab test in *LaCorte v.*

SmithKline) will be encompassed by the earlier qui tam action for first to file purposes if it is part of the same fraudulent scheme alleged by the first in time relator. Accordingly, it is important to note that this Court's decision in *Abbott* was based on its careful examination of facts unique to Erythromycin and not limited to reasoning inconsistent with the later *Duxbury* opinion. In *Abbott*, the Court concluded that the marketing and pricing of self-administered drugs typically purchased by patients at a retail pharmacy (such as those involved in the later Erythromycin case) was significantly different from the marketing and pricing of intravenously administered products by an entirely separate division of the drug manufacturer when the IV products were typically purchased and administered by physicians and specialty health care providers. In the present case, both Recombinate and Advate (as well as the other Baxter biological products alleged by Ven-A-Care) were marketed and priced by the same Baxter biologics division and were typically purchased and administered by health care providers; therefore, the essential facts are the opposite of those in the Abbott case. Indeed, Sun/Hamilton's own pleadings reveal that Baxter is alleged to have included Recombinate and Advate in the same fraudulent scheme by reporting inflated prices/costs to First Data Bank knowing that they would be marked up to calculate an inflated AWP that would in turn be reported to the Medicare and Medicaid programs, causing them to pay inflated reimbursement. Sun/Hamilton assert that Advate was an improved product "developed to replace Recombinate"; that it was "unlike Recombinate or any other *competitive product";* and that its features had unspecified "implications" for different marketing and pricing fraud. (Reply at 11) [emphasis added]. Neither this attempted differentiation nor Sun/Hamilton's pleadings describe a new and different fraud scheme – only

an improved version of blood factor VIII recombinant marketed through the same fraudulent scheme that Ven-A-Care had already alleged and alerted the government to.

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Respectfully submitted,

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By: /s/ James J. Breen
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document, filed this ____ day of _____, 2012 via the Court's ECF system, will be sent electronically by the ECF system to the registered participants as identified on the Notice of Electronic File (NEF) and to be served on all counsel of record via electronic service by sending a copy to LexisNexis File & serve for posting and notification to all parties.

By:_____
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